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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/898,770	07/02/2001	Edward M. Lichten	20013810-0003	4869

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EXAMINER
SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 04/08/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/898,770	LICHTEN, EDWARD M.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01/22/2003 as Paper Number 3* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-65* is/are pending in the application.

4a) Of the above claim(s) *1-35,40,44,45,49 and 51-65* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *36-39,41-43,46-48 and 50* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's response filed January 22. 2003 as Paper Number 3 to election requirement in Office Action mailed December 19, 2002 as paper Number 2 is acknowledged and entered.

2. Claims 1-65 are pending.

Restriction/Election

3. Applicant's election of Group IV, Claims 36-51 filed January 22. 2003 as Paper Number 3 in response to election requirement in Office Action mailed December 19, 2002 as paper Number 2 is acknowledged and entered. Applicant's election, of insulin as the therapeutic agent, diabetes related diseases as group of disorders and percutaneous mode of administering for said therapeutic agent as the species for prosecution of this application in response to Office Action mailed December 19, 2002 as paper Number 2 is also acknowledged.

Since the election is made without traverse, the restriction requirement is deemed proper and is made FINAL.

Accordingly, Claims 1-35 and 52-65 are withdrawn from further consideration as being directed to a non-elected invention. Claims 40-44, 45, 49 and 51 are withdrawn from consideration as being drawn to a non-elected species, the elected species having been found unpatentable (*vide infra*). See 37 CFR 1.142(b) and MPEP § 821.03.

4. Claims 36-39, 41-43, 46-48 and 50 are examined on merits insofar as they read on the elected species.

Priority

5. Applicant's claim for domestic priority under 35 U.S.C.§120 is acknowledged. However, the Examiner does not have an access to non- provisional application upon which priority is claimed. Therefore, pending availability of non-provisional U.S. application Number 09/198,798 dated November 24, 1998 the instant application is given benefit of the filing date i.e., 07/02/2001) for instant non-provisional U. S. Application Number 09/898,770.

Claims Objection

6. Claims 36(i)- 36(iii) and 37-38 are objected to because those claims do not have any relationship with step recited in Claim 36(iv). As presently recited, the amount of therapeutic agent administered according to the step in claim 36 (iv) does not depend on the steps recited in Claims 36 (i) – 36(iii) or to determine F factor.

Claim Rejections – 35 U.S.C. § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> ***A person shall be entitled to a patent unless –***
>
> ***(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.***

8. Claims 36 (iv), 39, 41, and 46-48 are rejected under 35 U.S.C. §102(b) as anticipated by Cavazza (U.S. Patent 4,362,719).

Claims recite a method to administer a therapeutic agent (i.e., insulin) to an individual having a disorder associated with a hormonal disorder, wherein said disorder is diabetes or diabetes related disease (e.g., hyperinsulinemia, hyperglycemia) and the therapeutic agent is administered to a human.

Cavazza discloses a therapeutic method to treat juvenile diabetes mellitus human patients via administering to said patients a composition comprising insulin to overcome the deficiency of insulin secretion or insulin shock (i.e., hypoglycemia), wherein the daily insulin dose is reduced by 20-50% (Column 1, Lines 6-25 and Column 8, Lines 4-25). Please note that insulin is a hormone therefore, insufficient insulin secretion is a hormonal disorder manifested as diabetes mellitus or hyperglycemia. Also, in the prior-art disclosed therapeutic method, to balance hormonal (i.e., insulin) levels, insulin is administered to a human patient in need thereof. Thus, upon administering the composition to a patient with juvenile diabetes, according to prior art disclosed method, inherently, an increase in the level of blood insulin in contrast to blood insulin levels prior to administering the prior-art disclosed composition would occur. Furthermore, since the method discloses to administer said composition to a human patient having diabetes mellitus, the prior-art disclosed therapeutic method inherently discloses a method to treat hormonal imbalance in a male or

female patient, wherein the hormonal disturbance leads to diabetes related disease that is treated with at least one daily dose of insulin.

Therefore, the reference is deemed to anticipate the cited claims.

Claim Rejections - 35 U.S.C. § 103

9. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> ***(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.***

10. Claims 36(iv), 39, 41-43, 46-48 and 50 are rejected under 35 U.S.C. § 103 (a) as obvious over Cavazza (U.S. Patent 4,362,719) in view of English Abstract of Moinet et al. (WO 9747612).

Claims recite a method to administer a therapeutic to an individual having a disorder associated with a hormonal disorder, wherein said disorder is diabetes or diabetes related disease (e.g., hyperinsulinemia, hyperglycemia) and the therapeutic agent is administered as a dosage to a human male or female once or multiple times.

Teachings from Cavazza have been discussed *supra*. Cavazza, however, broadly teaches administration of a hormone (i.e., insulin) to overcome hormone imbalance, but is silent about how said hormone is administered.

English abstract of Moinet et al. teach a method to treat diabetes via percutaneous administration of a composition comprising insulin to control glycemia (Title and Abstract, Lines 14-17).

One having ordinary skill in the art would have been motivated to modify the teachings from Cavazza according to the teachings from Moinet et al. to percutaneously administer a composition comprising insulin to treat the hormonal balance, because Cavazza discloses a therapeutic method to treat juvenile diabetes mellitus human patients via administering to said patients a composition comprising insulin to overcome the deficiency of insulin secretion and English abstract from Moinet et al. teach percutaneous method of administering a composition to treat diabetes or control glycemia. Thus, English Abstract from Moinet et al. (Title and Abstract, Lines 14-17) remedies the deficiency of percutaneous

administration of a composition in Cavazza's teachings. Please note that insulin is a hormone and intrinsically insufficient insulin secretion is a hormonal disorder manifested as diabetes mellitus or hyperglycemia. Also, in the prior-art disclosed therapeutic method, to balance hormonal (i.e., insulin) levels, insulin is administered to a human patient in need thereof. Thus, upon administering the composition to a patient with juvenile diabetes according to prior art disclosed method, intrinsically, an increase in the level of blood insulin in contrast to blood insulin levels prior to administering the prior-art disclosed composition would occur. Furthermore, since the method discloses to administer said composition to a human patient having diabetes mellitus, the prior-art disclosed therapeutic method intrinsically discloses a method to treat hormonal imbalance in a male or female patient, wherein the hormonal disturbance leads to diabetes related diseases.

Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to modify teachings from Cavazza according to the teachings from Moinet et al. to treat hormonal balance in a human resulting into diabetes mellitus by percutaneously administering a composition comprising insulin.

From the teachings of the cited references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

None of the above discussed prior art references teach the frequency or dosage of insulin administration. However, the adjustment of particular conventional working conditions (e.g., dosage of a particular pharmaceutical or therapeutic composition and frequency of administering the dosage.) is deemed merely a matter of judicious selection and routine optimization, which is well within the purview of the skilled artisan.

Conclusion

11. No Claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday-Thursday from 7:30 A.M. to 6:00 P. M. (Eastern Standard Time or Eastern Daylight Saving Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Patent Examiner
Art Unit 1651
(703) 605-1196

April 7, 2003

Jon P. Weber, Ph.D.
Primary Examiner